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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,987	10/23/2003	Steven M. Griffiths	11201-728-999	4737
20583	7590	07/07/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			HAN, MARK K	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/690,987

Applicant(s)

GRIFFITHS ET AL.

Examiner

Mark K. Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group IV, Species XII in the reply filed on 07 November 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07 November 2005.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,685,846 to Michaels, Jr.

Michaels, Jr. discloses an injection device having a chamber that includes a seal structure 45, a wet compartment 39, dry compartment 37 and a needle assembly 35. See Figures 1-10. See also col. 3, line 31 through col. 5, line 44. Michaels, Jr. does not expressly disclose a specific way of loading the syringe medicaments. One way is to seal the front end, add solid medicament, insert the seal structure, add liquid medicament and then seal the rear with the

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plunger. Another method is to do the reverse. Another method is that disclosed by the applicant. A user has a number of permutations in which the user can fill the chamber. The method disclosed by the applicant is one obvious method. It would prevent any reaction between the two medicaments. If using the method first described above, then one would have to clean out the liquid medicament chamber after inserting the seal structure but before adding the liquid because there may be some solid material on the wall of the barrel. If there is solid on the inside wall, it may affect dosage, the purity of the liquid medicament and ineffectiveness of the ultimate drug administration. Therefore, it would have been obvious to one of ordinary skill in the art to choose a method of filling a chamber having the structure disclosed by Michaels, Jr., by inserting the seal structure first, and then filling and sealing either end of the chamber in order to maintain the integrity of the two medicaments.

4. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels, Jr. in view of U.S. Patent No. 4,822,340 to Kamstra.

Michaels, Jr. discloses the claimed invention as shown above. Michaels, Jr. discloses a dry medicament, but does not disclose that it is in tablet form. Kamstra suggests that the dry medicament may be in tablet form. See col. 10, lines 1-3. It would have been obvious to one of ordinary skill in the art to modify the invention of Michaels, Jr. by preparing the dry medicament in tablet form, as suggested by Kamstra, to enhance portability of the medicament.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 29-36 have been considered but are moot in view of the new ground(s) of rejection.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER



Mark K. Han  
Patent Examiner  
Art Unit 3767

mkh  
June 26, 2006